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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant:	Jeremy Francis Donnan et al.
Invention:	HYPODERMIC SYRINGES
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Michelle L. Davis

CLAIM FOR PRIORITY

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Sir:

Applicants hereby claim the priority of United Kingdom Patent Application No. 0312036.7 dated May 27, 2003, under the provisions of 35 U.S.C. 119.

A Certified copy of the priority document is enclosed herewith.

United Kingdom Patent Application No. 9926505.0 filed November 10, 1999, has previously been provided to the U.S. Patent and Trademark Office in parent application serial number 09/707,176 filed November 6, 2000, now U.S. Patent No. 6,454,745.

Respectfully submitted,

Anthony Niewyk, Reg. No. 24,871
BAKER & DANIELS
111 East Wayne Street, Suite 800
Fort Wayne, Indiana 46802

AN/mld/295493

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

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Dated 27 June 2003

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Request for grant of a patent

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The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference — TC-MP100401-GB

2. Patent application number *(The Patent Office will fill in this part)* — 27 MAY 2003 — 0312036.7

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

   07243348002
   Patents ADP number *(if you know it)*

   If the applicant is a corporate body, give the country/state of its incorporation

   NMT Group plc
   New Medical House
   Oakbank Park
   Livingston, West Lothian
   Scotland EH53 OTH

4. Title of the invention — HYPODERMIC SYRINGES

5. Name of your agent *(if you have one)*

   "Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

   Lloyd Wise, McNeight & Lawrence
   Regent House, Heaton Lane
   Stockport, Cheshire SK4 1BS

   Patents ADP number *(if you know it)* — 0845 827 5001 ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
GB	0222166.1	25/09/2002

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*
   a) any applicant named in part 3 is not an inventor, or
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Abstract	
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Request for preliminary examination and search *(Patents Form 9/77)*	
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Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature: Lloyd Wise, McNaught & Lawrence

Date: 23 May 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

A R Collingwood
0161 480 6394

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HYPODERMIC SYRINGES

This invention relates to the fitting of needle components to the barrel of a hypodermic syringe.

It is common practice to fit a syringe with a filling needle for the purpose of drawing liquid into the barrel of the syringe, by retraction of its plunger, from a vial often of the kind having a rubber cap which is penetrated by the filling needle. After the syringe has been charged, the filling needle is removed and replaced by a needle to be used for administration of an injection into a patient. Yet again it is often necessary to change a needle to meet patient requirements.

During the change of needle where the syringe barrel is of a type having a large open end to permit needle retraction, care must be taken to avoid spillage of the contents of the syringe through the open end of the barrel especially when the barrel is inverted so that its open end is directed downwardly.

It is already known from our UK Patent Application No. 2356144 to provide a seal for the open end of a barrel, the seal being in the form of a cap which is fitted externally over the open end of the barrel and has a central aperture which is sufficiently small as ordinarily to retain liquid therebehind but which can be deformably expanded to allow passage of the rearward end of a needle hub for engagement with the barrel.

It is an object of the present invention to provide a restrictor for the open end of a syringe barrel which overcomes the problem aforesaid in a manner such that fitting of the filling and injection needles to the barrel is simplified.

According to the present invention there is provided a barrel for use with a retractable needle assembly comprising a needle and a mounting hub for the needle, the barrel being provided with a restrictor located internally of the barrel at or adjacent an open end of the barrel, the restrictor having at least one aperture which is sufficiently small as ordinarily to retain liquid within the barrel and being adapted to allow passage of the needle and a mounting hub into the barrel.

In this manner, liquid introduced into the barrel, for example by means of a filling needle unit, may be prevented from "glugging" out of the barrel while the filling needle unit is being replaced by an injection needle unit, such egress of the liquid being restricted by virtue of surface tension effects associated with an aperture or apertures having appropriately small dimensions for the liquid involved.

In particular if, after uncoupling of the filling needle unit and before coupling of an injection needle unit of the retractable type, the barrel is handled normally, the risk of the liquid drug "glugging" out of the barrel is significantly reduced by the restrictor. Thus, for a water-based drug having, at a temperature of 20°C, a viscosity of about 1 cP and a surface tension of about 73 dynes/cm, if the barrel is pointed downwardly, the restrictor will be capable of preventing liquid spillage at least as long the barrel is subjected to normal handling and is not shaken violently.

The aperture may take various forms and the term as used herein is to construed as including a passageway along which the liquid can pass.

Typically the retractable needle unit comprises a needle, a mounting hub therefor, a restrainer for holding the hub in a forward position and a retraction mechanism operable, upon release of the hub from the restrainer, to drive the needle and mounting hub rearwardly from said forward position into the barrel.

The plunger may co-operate directly with the restrainer to effect release of the hub or alternatively at or near the end of its forward stroke of the plunger, the forward end of the plunger may contact the restrictor so that forward movement of the plunger is transmitted through the restrictor to the restrainer in order to effect release of the hub.

The liquids employed will usually have, at a temperature of 20°C, a fluid viscosity in the range of 0.6 to 70 cP and a surface tension in the range of 20 to 100 dynes/cm.

The plunger is typically hollow and the retraction mechanism is operable to drive the needle into the hollow plunger.

The plunger may have a forward end which approaches said open end of the barrel during discharge of liquid from the barrel and may have at its forward end a part which closes said forward end but is severable or dislodgeable from said forward end to allow the needle and mounting hub to be driven by the retraction mechanism into the hollow plunger.

The restrictor may be a component separate from the barrel or it may be integral with the barrel.

The restrictor may be deformable, e.g. resiliently deformable, at least in the region of said aperture to allow passage of the needle and mounting hub therethrough.

The restrictor may include a sealing formation which co-operates with part of the needle unit whereby, during an injection stroke of the plunger, discharge of liquid from the unit is confined to the pathway provided by the needle.

Said aperture may comprise a single hole which may be circular or which may be provided with one or more inwardly directed projections for enhancing the ability of the restrictor to prevent egress of liquid from the barrel. For example, the periphery of said aperture may be of a castellated configuration formed by said projections.

The projection or projections may be capable of flexing to allow such passage of the needle and hub.

In some embodiments of the invention, said aperture of the restrictor may be sized so that the hub and needle can pass therethrough during needle retraction.

In other embodiments, said aperture may be of a size which is not sufficient to allow passage of the hub and needle. In such embodiments, the restrictor may include a portion which can be removed, e.g. broken away or dislodged, to allow passage of the needle and hub during the needle retraction process. Another alternative is for the restrictor to be capable of being disrupted, e.g. by virtue of being made of a brittle or frangible material, in such a way that it no longer blocks the needle and hub when needle retraction is required.

The restrictor may comprise an inner portion and an outer portion, the inner portion being severable or otherwise releasable from the outer portion to create an opening sufficiently large to allow passage of the needle and hub during needle retraction.

The inner and outer portions may be demarcated from one another by a zone or line of weakness (e.g. generally circular) at which the inner portion is severable from the outer portion during needle retraction. The zone or line of weakness may be provided by one or more webs of material interconnecting the two portions.

The inner and outer portions may alternatively be interconnected at a moulding interface therebetween such that the inner portion is severed or dislodged from the outer portion as the plunger approaches or reaches completion of its forward stroke.

The inner portion may be provided with said aperture.

The inner portion may be of tubular configuration defining a passageway constituting said aperture.

In one embodiment of the invention, the restrictor may comprise a disc located within the barrel.

When *in situ* within the barrel, the disc may be of generally conical configuration with an aperture at its "apex" and with its apertured "apex" located forwardly of the outer periphery of the disc.

The configuration of the disc, when in situ, may be such as to include an obtuse cone angle, typically of the order of 140°.

The disc may be thin and flat when manufactured so that it can be pressed or cut out of strip or sheet material, injection or compression moulded or produced by

other techniques so that the disc is not "handed" when manufactured but can take up the conical configuration.

Alternatively the disc may be manufactured with a generally conical configuration, e.g. by moulding.

The aperture in the disc may be a plain circular hole or it may be of other configuration. For example, its periphery may be provided with one or more fingers which will have the effect of reducing the apparent hole cross-section, thereby enhancing its ability to seal against liquid egress from the barrel.

The periphery of the aperture may be of castellated configuration, e.g. by virtue of one or more fingers as referred to above.

Where the aperture periphery is provided with a finger or fingers and/or a castellated configuration, the arrangement may be such that the finger or fingers or other such projections are capable of flexing to allow passage of the needle and hub.

The disc may be self-retaining in the barrel once inserted. Its outer periphery may if desired engage with a shoulder or within a groove in the wall of the barrel so that the disc is prevented from being dislodged.

The outer periphery of the disc may be provided with one or more fingers and/or be castellated to aid its deformation during insertion into the barrel and/or aid its retention once inserted into the barrel.

Typically the material of which the disc (or other form of restrictor) is composed may be a deformable polymeric material or an elastomeric material suitable

for use in a medical syringe. The material may for instance be one which is suitable for exposure to gamma radiation and/or ethylene gas sterilisation.

The arrangement may be such that when the needle and hub assembly is fitted to the barrel, the rearward end of the needle/hub unit is located forwardly of the disc.

In another embodiment of the invention, the restrictor may be in the form of an annular flange projecting inwardly of the barrel and, optionally, rearwardly also, the flange defining an aperture which is sufficiently small as ordinarily to retain liquid within the barrel. This embodiment is particularly suitable for barrels which have a relatively low filling capacity, e.g. of the order of 1 cc.

The flange may be resiliently deflectable radially outwardly.

The flange may be formed integrally with the barrel adjacent its open end.

The flange may function also as a lip seal by co-operation with a component of the needle unit, e.g. by co-operation with a component which restrains the needle hub against retraction until the plunger approaches or reaches the end of its forward stroke.

In a further embodiment of the invention, the restrictor may be perforated or reticulated to prevent "glugging" of the liquid out of the barrel.

The restrictor may present an array of apertures distributed over the cross-sectional area of the barrel.

The restrictor may be of a frangible or brittle material or rendered frangible or brittle in a defined zone or zones thereof so that, during forward movement of the plunger, the integrity of the restrictor is disrupted to allow passage of the hub/needle assembly during needle retraction.

In yet another embodiment of the invention, the restrictor may comprise an inner part and an outer part which are normally coupled together but which are released from one another as the plunger approaches or reaches completion of its forward stroke.

The outer part may be restrained against forward movement or only allowed to move forwardly to a limited extent relative to the barrel.

After release of the inner part from the outer part, the inner part may leave an opening in the restrictor sufficiently large to allow passage of the needle/hub assembly during needle retraction.

The inner part may be provided with a central passageway for liquid flow into and out of the barrel, the passageway being sufficiently small as ordinarily to retain liquid within the barrel when pressure is not being applied to the plunger to move it forwardly.

The restrictor may be provided with an additional opening or openings of this nature in the outer part.

The two parts of the restrictor may be coupled together by moulding one part in the presence of the other part, e.g. by a two-shot moulding process, as disclosed

in International Patent Application No. PCT/GB 02/01865, the entire contents of which are incorporated herein by this disclosure.

Alternatively the two parts may be coupled together via frangible sections of material which can readily break to allow release of the inner part from the outer part when required. For instance, the restrictor may be moulded from plastics material with thin webs of the plastics material interconnecting the two parts.

The hub and the restrainer may be formed, e.g. by a 2-shot moulding process, as plastics mouldings in such a way that the restrainer is axially captive with the hub, e.g. as disclosed in our prior International Patent Application No. PCT/GB 02/01865, the entire contents of which are incorporated herein by this reference.

The arrangement may be such that the injection needle unit is engaged with the barrel through a one-way coupling means formed by interfitting components on the needle unit and the barrel whereby the injection needle once assembled to the barrel cannot be disengaged from the barrrel (at least not without damaging the components).

The one-way coupling means may comprise a threaded connection or a bayonent-type connection between a male part and a female part, one part being associated with the barrel and the other part being associated with the injection needle.

The one way coupling means may for example comprise a threaded connection between a male and a female part, there being a void in an upstanding portion of the thread on each part and a barb in the void on one of the parts, the arrangement being such that when the parts are threadedly engaged, resilient deformation of at least one of the parts enables the barb to latch behind an end of a

thread at the void in the other of the parts to prevent subsequent disconnection of the parts. Such an arrangement is disclosed in our prior UK Patent Application No. 2353078, the entire disclosure of which is incorporated herein by this reference.

The coupling may be such that an internal thread section provided on the needle unit engages with an external thread on the barrel, or *vice versa.*

The invention will now be described by way of example only with reference to the accompanying drawings, in which:

Figure 1 is a longitudinal sectional view showing the barrel of a hypodermic syringe fitted with a filling needle and sheath unit, the unit being provided with a restrictor in accordance with a first embodiment of the invention;

Figure 2 is a view similar to Figure 1 but showing the filling needle assembly removed from the barrel and the barrel filled with liquid;

Figure 3 is a view similar to that of Figure 2 but wherein the barrel is about to be fitted with an an injection needle assembly;

Figure 4 is an enlarged view showing the injection needle assembly fitted to the barrel;

Figure 4A is a schematic view showing the periphery of the aperture formed in the restrictor;

Figure 5 is a fragmentary perspective view in section of a syringe shown fitted with an injection needle of the retractable type, provided with a restrictor in accordance with a second embodiment of the invention;

Figure 6 is a diagrammatic sectional view of a syringe showing a modification applicable to the embodiment of Figure 5;

Figure 7 is a fragmentary perspective view of another embodiment of the invention in which the restrictor is in the form of a frangible disc or the like;

Figure 8 is a fragmentary perspective view of yet another embodiment in which the restrictor is of two part form allowing the central part to be produced with a passageway smaller than the lateral dimensions of the needle hub;

Figure 9 is an enlarged perspective view of the restrictor of the embodiment illustrated in Figure 8;

Figure 10 is a fragmentary perspective view of a further embodiment in which the restrictor comprises an outer part and a central part; and

Figure 11 is an enlarged perspective view of the restrictor of the embodiment illustrated in Figure 10.

The syringe of the present invention, when fitted with an injection needle unit of the retractable type, may be a hypodermic needle syringe as described in for example our prior International Patent Application No. PCT/GB 02/01865. Typically,

in such a syringe the plunger has a forward end which approaches the open end of the barrel during discharge of liquid from the barrel and has at its forward end a part which can be severed or dislodged from the forward end of the plunger. The needle unit comprises a needle, a mounting hub therefor, a restrainer for holding the hub in a forward position and a retraction mechanism operable, upon release of the hub from the restrainer, to drive the needle and mounting hub rearwardly from said forward position into the hollow plunger. The severable part is severed from the forward end of the plunger prior to or during operation of the retraction mechanism. Release of the hub from the restrainer is effected by co-operation of the forward end of the plunger with the restrainer whereby forward movement of the plunger at or near the end of the forward stroke thereof is effective to displace the restrainer and effect release of the hub and the needle.

Referring to the drawings, the tubular barrel 10 of a syringe is open at its forward end 12 and is fitted with a restrictor in the form of a non-latex, resiliently deformable disc or washer 14 having a central opening 16. In its relaxed state, the washer 14 may be flat having a diameter which is slightly greater than the internal diameter of the barrel at its forward end 12. When the washer 14 is pressed into the interior of the barrel, it takes up a slightly conical form by virtue of its diameter being slightly greater than the barrel internal diameter. This facilitates securing the washer in place at the forward end of the barrel. Instead of the washer being initially flat, it may instead be manufactured with a conical configuration. The periphery of the washer 14 contacts the internal wall of the barrel 10 and because of its conical configuration resists displacement in the rearward direction during filling of the barrel.

It will be understood that the washer need not be of conical configuration as long as it is secured in such a way that it is not displaced rearwardly during filling of the barrel. To facilitate location of the washer (whether conical or not), the barrel may

be provided with an internal groove or shoulder 18 in or against which the washer 14 seats. When the washer is in situ in the barrel, the opening 16 is presented forwardly of the outer periphery of the washer. Although not shown, the forward end of the barrel may have a conical end formation located forwardly of the washer such that the washer, when inserted, takes up the form of the forward end of the barrel.

In Figure 1, the barrel is shown fitted with a unit comprising a filling needle 20 and a protective sheath 22, the unit being coupled to the forward end of the barrel by a screwthreaded connection between the rearward end portion 24 of the unit 20, 22 and a forwardly projecting collar 26 of the barrel. The sheath 22 is designed to be broken off when the user is ready to use the filling needle so that the needle 20 can be inserted into a vial or other source of fluid which is to be drawn into the barrel in the usual way (involving retraction of a plunger, not shown, rearwardly along the barrel). As the fluid is drawn into the barrel, it flows directly through the opening 16 at the centre of the washer 14 and into the evacuated volume of the barrel.

At this point, it is necessary to replace the filling needle unit with the injection needle unit. The filling needle is decoupled from the barrel 10 (see Figure 2) and the injection needle unit is then fitted to the barrel (see Figures 3 and 4). If now the barrel is handled normally, e.g. inverted or shaken (but not unduly violently), the risk of the liquid drug "glugging" out of the barrel is significantly reduced by virtue of the washer 14 since the opening 16 forms a small hole at the base of a liquid filled chamber, namely the barrel, and is designed so that, because of the surface tension properties of the liquid, it cannot allow air in and liquid out at the same time, with the consequence that there is no flow either way. In this way, during interchange of needles, the liquid is retained in the barrel by the washer 14 provided that the barrel is not subjected to any unduly violent shaking or handling.

The injection needle unit comprises a mounting portion 28 for coupling to the barrel, an injection needle 30 carried by a hub 32 and a restrainer constituted by a crown 34. The hub 32 and needle 30 are biased rearwardly by a spring 36 for retraction at the appropriate time into the barrel and associated hollow plunger within the plunger. As disclosed in prior International Patent Application No. PCT/GB 02/01865, the hub 32 and crown 34 may be formed by a 2-shot moulding process so that they are captive with each other until the crown is displaced by collar 37 (see Figure 4) of the plunger so to decouple the hub 32 and crown 34 and release the hub and needle for spring-driven travel into the barrel and plunger. It will be noted that, during the needle release operation, forward motion of the collar 37 is transmitted to the crown 34 via the washer 14 which is resiliently deformable. However, it will be understood that the present invention is not limited to triggering of the needle retraction mechanism in the manner just described; other methods known in the art may be used for retaining the hub and needle and releasing the same when needle retraction is required.

Prior to, during or just after release of the hub from the crown, the leading end 38 of the plunger will also be separated from the plunger and be driven into the interior of the plunger. In this context, the leading end of the plunger may, but need not necessarily, be produced as a 2 shot moulding as disclosed in International Patent Application No. GB00/04573, the entire disclosure of which is incorporated herein by this reference.

The gap between the forward end of the washer 14 and the rearward end of the crown is minimised to reduce drug wastage. It will be noted that the dimension of the hub is such that the hub and also the spring 36 may pass freely through the opening 16 in the washer once needle retraction has been initiated as a result of contact between the trailing end part of the crown 34 and the leading end 38 of the plunger.

The coupling between the mounting portion of the injection needle unit and the barrel is conveniently a one-way coupling as referred to above and may be implemented for example in the manner disclosed in UK Patent Application No. 2353078. Fitting of the filling needle assembly may be through a similar coupling means except for the omission of the locking barbs so that, in contrast with the injection needle unit, the filling needle unit may be readily removed when finished with.

In the embodiment of Figures 1 to 4, the opening 16 in the disc is circular; however, it may be of other configuration consistent with making use of surface tension effects to prevent the liquid "glugging" out of the barrel. For instance, the opening 16 may be of castellated configuration as illustrated in Figure 4A so as to reduce the cross-sectional area of thereof, the projections extending radially inwardly but being readily deflectable so that they do not obstruct passage of the needle/hub assembly after needle retraction has been triggered.

Referring now to Figure 5, in this embodiment the restrictor is constituted by an annular projection or flange 100 provided internally of the forward end of the barrel 102. The restrictor in this case may be formed integrally, as by plastics moulding, with the barrel. As shown in Figure 5, the syringe is shown in a configuration in which the injection needle has been fitted following filling of the barrel with filling needle unit and removal of the latter. The hub 112 and crown 108 in this embodiment are coupled together at the moulding interface 126 by two-shot moulding in such a way that the parts are mechanically connected and possibly also fused or adhered together at the interface. Such an arrangement may also be employed in other embodiments of the invention illustrated herein.

Prior to fitting of the injection needle unit 103 and its sheath (not shown), it will be understood that the restrictor 100 will be effective to prevent spillage of liquid from the filled barrel provided that the diameter of the restrictor is sufficiently small. When the invention is implemented in this manner, the dimension of the opening in the restrictor 100 is determined by the need to allow passage of the assembly comprising the needle 110 and hub 112 during operation of the needle retraction mechanism. For this reason, this implementation of the invention is primarily intended for low capacity and hence small diameter syringes, e.g. syringes having a filling capacity of the order of 1ml. In this case, the dimensions of the various parts can be made smaller, consistent with securing a restrictor hole sufficiently small that, for liquids in the viscosity range typically encountered for liquids to be administered by injection, the risk of egress of liquid from the barrel is prevented in normal use. As previously mentioned, typical properties for liquids to be used with syringes in accordance with the invention are a fluid viscosity in the range of 0.6 to 70 cP (typically about 1 cP) and a surface tension in the range of 20 to 100 dynes/cm (typically about 73 dynes/cm).

The restrictor 110 in the embodiment of Figure 5 serves the additional function of providing a seal between the crown 108 and the internal wall surface of the barrel, being in the form of a resiliently deflectable lip seal so arranged that, during the forward stroke of the plunger (not shown), the lip seal extends inwardly and rearwardly so that it tends to deflect radially inwardly due to the pressure exerted thereby enhancing the sealing action. It will be seen that, when the crown 108 is in place and engages with the lip seal/restrictor 100, it deflects the lip seal/restrictor 100 radially outwardly. When the crown 108 is not present, the lip seal/restrictor 100 is in a relaxed undeflected condition in which the central hole is of reduced diameter compared with the diameter it expands to when the lip seal is deflected outwardly by the crown 108.

Operation of the syringe of Figure 5 is generally similar to that described with reference to Figures 3 and 4 above and also to the syringe disclosed International Patent Application No. PCT/GB 02/01865 to which reference should be made for a more detailed description. After the barrel has been filled and the filling needle unit has been removed, the lip seal/restrictor 100 serves to retain the contents of the barrel awaiting fitting of the injection needle unit. Once the injection needle unit has been fitted, immediately prior to administering an injection, the needle sheath (not shown) is removed. Following insertion of the needle into the patient and operation of the plunger to force the contents of the barrel through the needle 110, the plunger eventually contacts and displaces the crown 108 forwardly to release the needle 110 and hub 112. At this time, the blocking portion 114 of the plunger 106 is also released to allow retraction of the needle and hub assembly into the hollow plunger, such retraction being effected by spring 116..

Figure 6 illustrates a modification of the embodiment of Figure 5 in which the restrictor 200 may again function as a resiliently deflectable lip seal but, at its inner periphery, is provided with an inwardly directed portion 220 which defines the aperture 222 through which the assembly of hub 212 and needle (not illustrated) of the injection needle unit can pass during needle retraction. The portion 220 may be integrally formed with the restrictor 200 which, in turn, may be integral with the barrel 202. The portion 220 may define a central circular aperture or alternatively the central aperture may be of other configuration, e.g. the portion 220 may be of castellated configuration or other configuration in which one or more parts project radially inwardly to a greater extent than other parts.

After the barrel 202 has been filled by means of the filling needle unit, it will be seen that egress of the liquid is restricted by the aperture 222. In the embodiment of Figure 6, the central aperture 222 may be somewhat smaller than its

counterpart in Figure 5 thereby permitting use of the restrictor 200 of Figure 6 with syringes over a wider range of filling capacities. During the forward stroke of the plunger 206, the forward end 224 of the plunger eventually contacts the portion 220 and continued pressure on the plunger is accompanied by displacement of the crown 208 and deflection of the restrictor 200 until needle retraction is triggered (by release of the hub from the crown at the interface 226) and the blocking portion 221 of the plunger is released, whereupon the hub and needle assembly is projected by the spring into the hollow plunger 206. Release of the blocking portion may occur just prior to, substantially simultaneously with, or just after release of the hub from the crown.

Figure 7 illustrates an embodiment in which the barrel 302 is provided with a lip seal 330 as in Figures 5 and 6 but, in this case, the lip seal need not function as a restrictor. In this embodiment, a separate restrictor 300 is provided which is perforated, reticulated or otherwise formed with openings 332 which allow admission of liquid into the barrel 302 during filling but which, by virtue of surface tension effects, prevent or reduce the risk of liquid egress from the barrel when the filling unit is removed. The restrictor 300 may be in the form of a perforated or reticulated disc located within the barrel and, at its outer periphery, is blocked against forward movement, e.g. by internal shoulder 334 of the barrel.

The restrictor 300 is adapted to to co-operate with the plunger 306 in such a way that, as the plunger approaches completion of its forward stroke, an opening is created in the restrictor 300 which is sufficient to allow the assembly of hub 312 and needle (not shown) to travel beyond the restrictor location. Such rearward travel of the hub and needle assembly can occur after the coupling at interface 326 is disrupted to allow hub release from the crown and the hub/needle assembly can then be driven into the hollow plunger 306 via the opening created by release of the blocking portion 338

from the rim portion 340 (at interface 342) as the plunger approaches or reaches completion of its forward stroke.

To allow the hub/needle assembly to pass through the restrictor, the restrictor 300 may be frangible so that it is broken by the forward advance of the plunger 306. For example, the restrictor 300 may be fabricated from a frangible or brittle material which will readily break or it may be formed with one or more lines or zones of weakness to allow part to be broken away to form the desired hole for passage of the needle and hub assembly.

Referring to Figures 8 and 9, in this embodiment the restrictor 400 comprises a central part 450 and an outer part 452 which are coupled together in such a way that, at a suitable point during the forward stroke of the plunger 406, the central part 450 is freed from the outer part 452 so that the assembly of hub 412 and needle (not shown) can be driven by the spring (not shown) into the hollow plunger 406 along with the central part 450. The central part 450 is provided with a passageway 454 through which liquid can pass during the filling and injection procedures. This passageway is suitably dimensioned so that the liquid filling the barrel 402 is retained within the barrel by surface tension effects during the time between removal of the filling needle unit and fitting of the injection needle unit. Typically the diameter of the passageway 454 may be of the same order as conventional Luer fittings for syringes - e.g. of the order of 2.0 mm. As in the embodiments of Figures 5 to 7, the barrel may be provided with a lip seal 430 for co-operation with the crown 408.

The coupling between the parts 450 and 452 may be secured by producing the restrictor 400 by two-shot moulding of one or more plastics materials such that they are engaged with each other at the moulding interface 456, e.g. in the manner disclosed for the hub and crown in International Patent Application No. PCT/GB 02/01865. As

previously mentioned, the coupling at the interface may be of a mechanical nature by contouring of the parts at the interface and/or it may involve fusion or adherence of the materials at the interface. However, it is to be understood that coupling arrangements, other than those created by two-shot moulding, may be used instead. The outer part may be of conical configuration, or adopt such a configuration when inserted into the barrel, with its outer periphery contacting the inner wall of the barrel 402 so that the restrictor 400 is readily movable in the forward direction but resists movement in the rearward direction.

In addition to the passageway 454, the outer part 450 may be formed with one or more openings in the form of for example apertures or cut-away portions 458 to provide further inlets for admission of the liquid during filling of the barrel. Such openings 458 will be dimensioned to prevent, by surface tension effects, liquid "glugging" out of the barrel 402. Of course, when the plunger 406 is pressed forwardly during the injection procedure, the liquid may exit via the openings 458 as well as through the passageway 454. By forming the openings 458 as cutaway portions as illustrated in Figure 9, radially projecting arms 460 are formed which impart additional flexibility to the outer part 452 so as to allow it to be readily moved in the forward direction while resisting rearward movement.

The restrictor 400 in located within the barrel 402 with a small amount of clearance X. When the plunger 406 approaches completion of its forward stroke during the injection procedure, the leading end of the rim portion 440 initially contacts collar 453 of the outer part 452 while the blocking portion or nose 438 contacts the central part 450. Continued forward movement of the plunger is then transmitted via leading end 462 of the outer part 452 to the crown 408 and brings the leading portion 464 of blocking portion 438 into abutment with the trailing end of the hub 412. The various parts are designed so that, in the process of taking up the clearance X, the central part

450 is released from outer part 452 of the restrictor, the hub 412 is released from the crown 408 and the blocking portion 438 is released from the rim portion 440. Once these conditions are secured, the hub and needle assembly can be driven by the spring (not shown) into the hollow plunger 406 along with the central portion 450 of the restrictor 400.

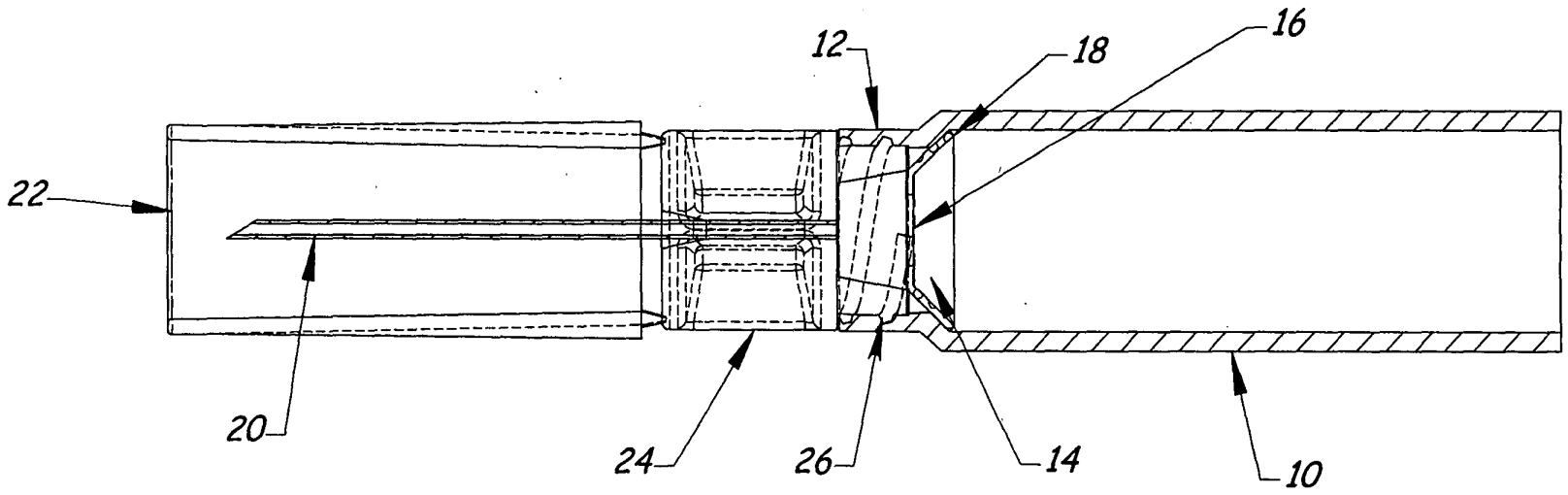
Figures 10 and 11 show a similar embodiment to that of Figures 8 and 9 in which the two parts 550 and 552 are coupled by narrow frangible sections or webs 566 instead of by two-shot moulding. The two parts may be produced as a single plastics moulding and webs 566 are defined by a circular array of openings 558 which surround the central part 550. A passageway 554 is also provided in the central part 550 and liquid ingress during filling takes place through the passageway 554 and the openings 558. Liquid egress however is restricted by surface tension effects to prevent glugging of the liquid out of the barrel 502 when the latter has been filled and is yet to be fitted with the needle injection unit.

As in the embodiment of Figures 8 and 9, forward movement of the plunger 506 is effective to release the various parts from one another by uncoupling the parts at the interfaces 426 and 542 and disrupting the narrow section webs 566 so that the central part 550 is freed to allow it together with the needle/hub assembly to be driven rearwardly into the hollow plunger 506 via the hole created by dislodging the blocking portion 538 from the rim 540.

In the embodiment of Figures 10 and 11, the outer part 552 is shown in the form of a conically-shaped disc with an uninterrupted outer periphery; however, if desired, its outer periphery may be provided with one or more cutaway portions as in the embodiment of Figures 8 and 9.

It will be appreciated that it is not intended to limit the invention to the above examples only, many variations, such as might readily occur to one skilled in the art, being possible, without departing from the scope thereof. Also certain features of the invention (for example the one-way coupling referred to in connection with the embodiment of Figures 1 to 4) which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment may also be provided separately or in any suitable sub-combination.

Figure 1



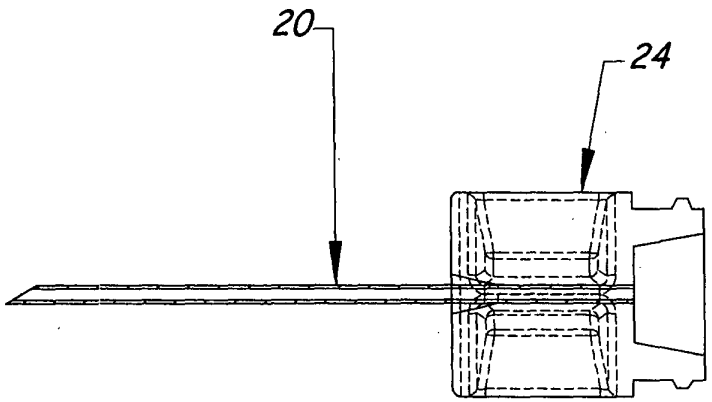


Figure 2

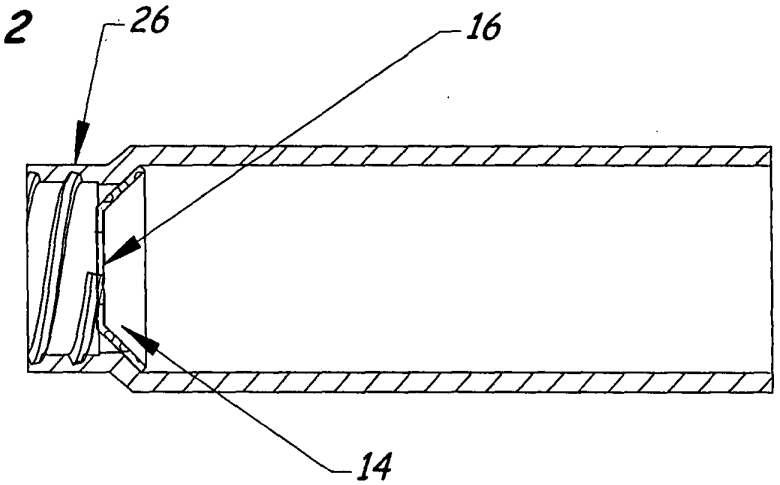


Figure 3

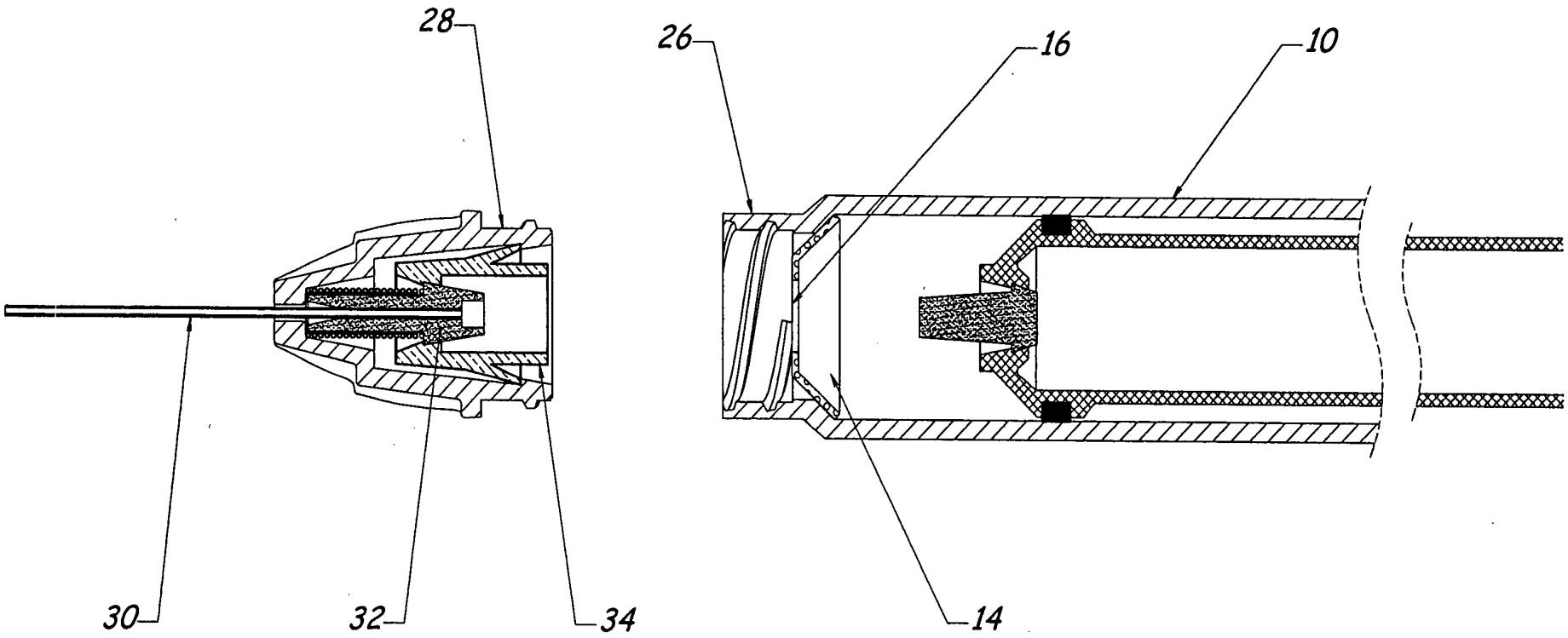


Figure 4

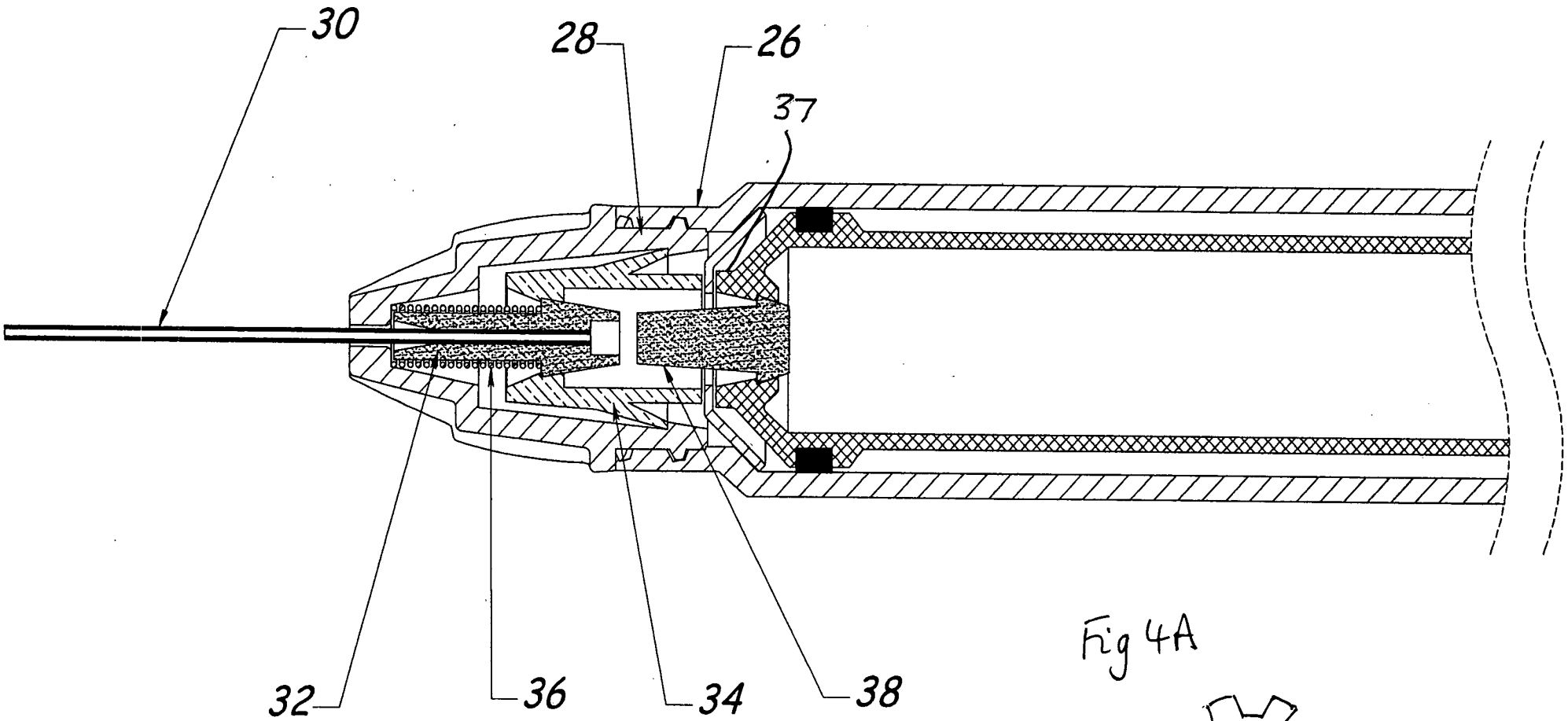


Fig 4A

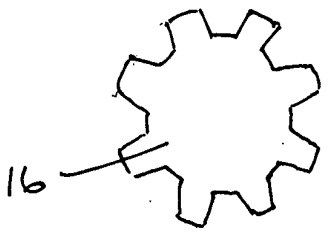


Fig 5

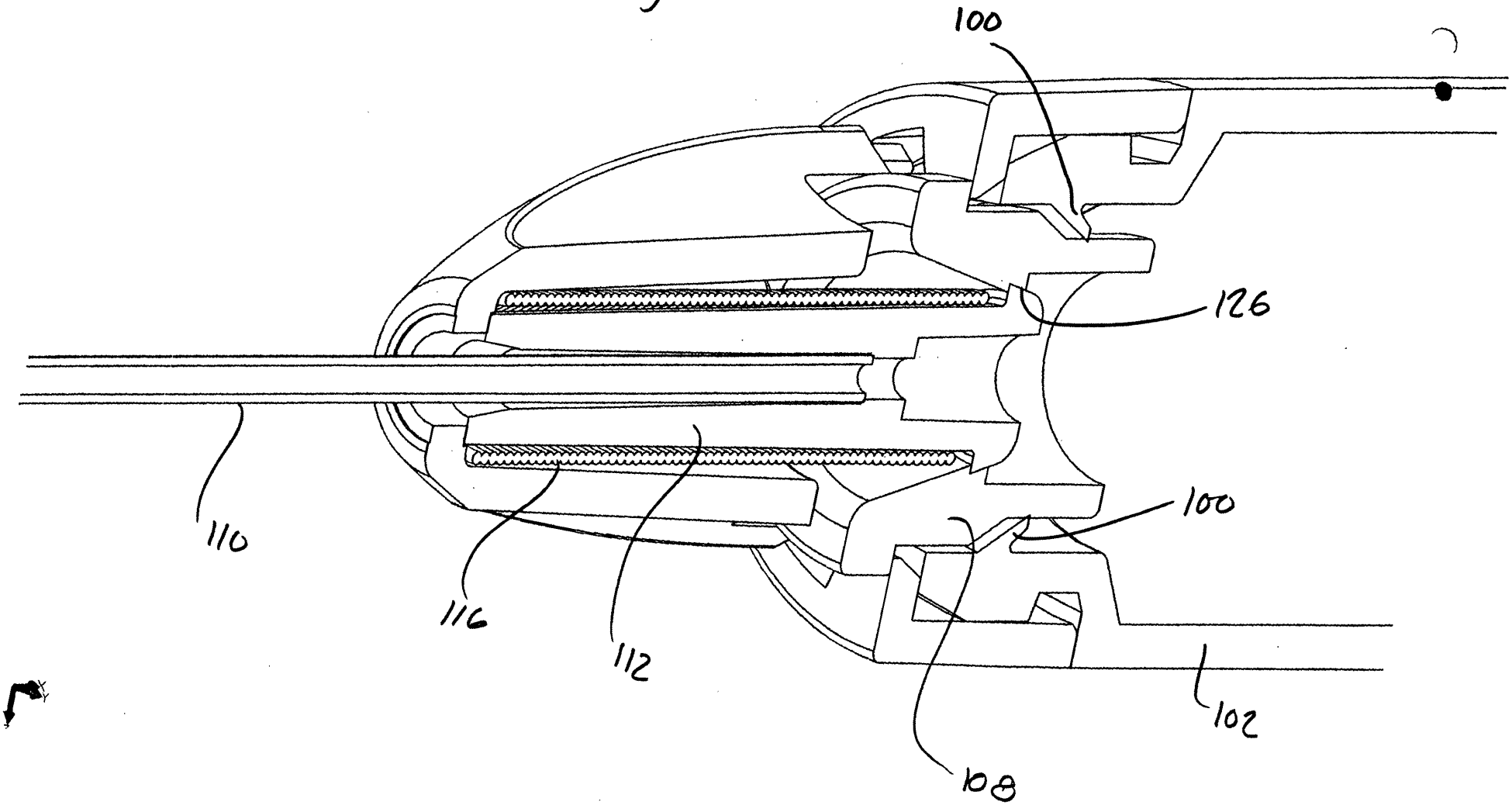
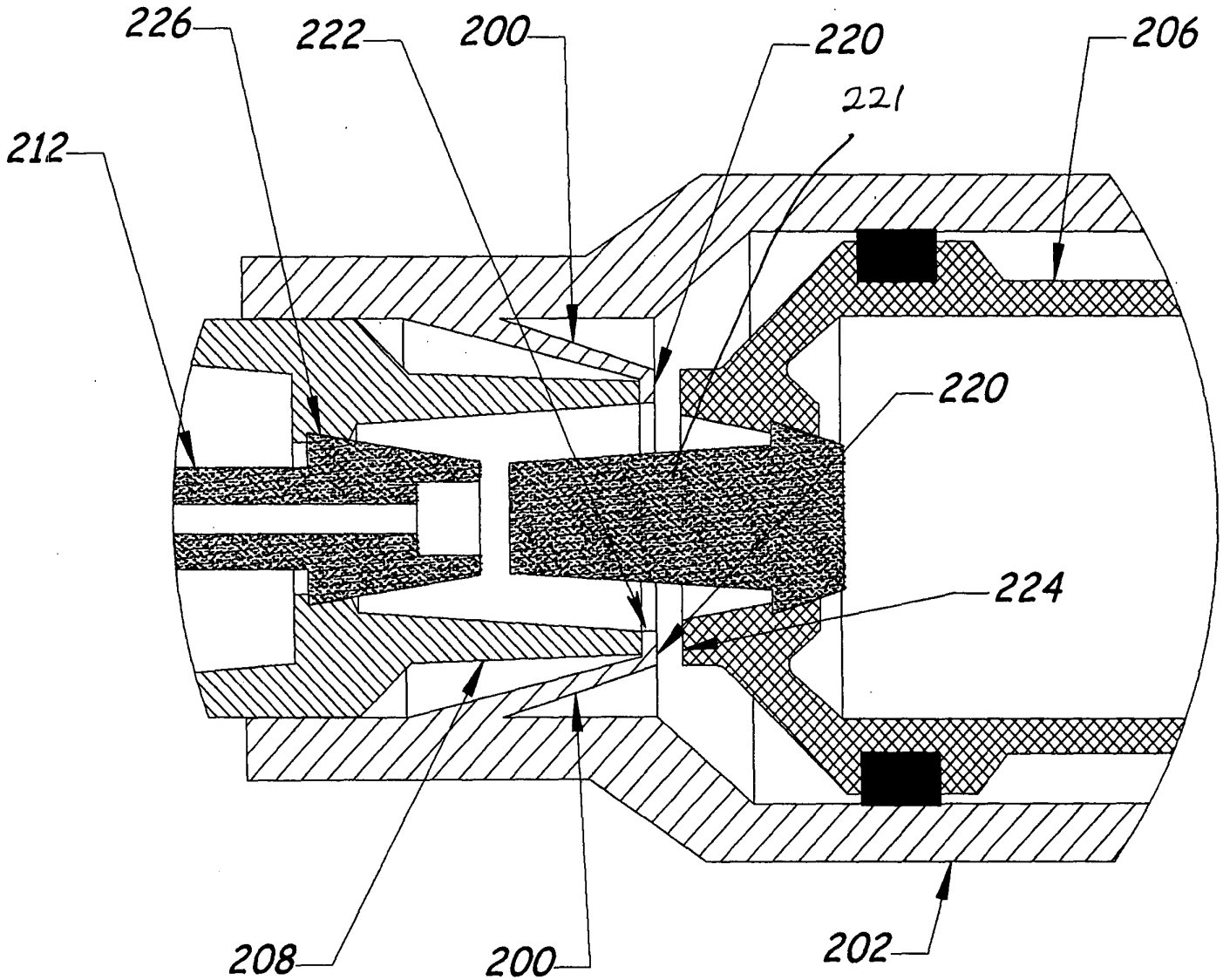


Figure 6



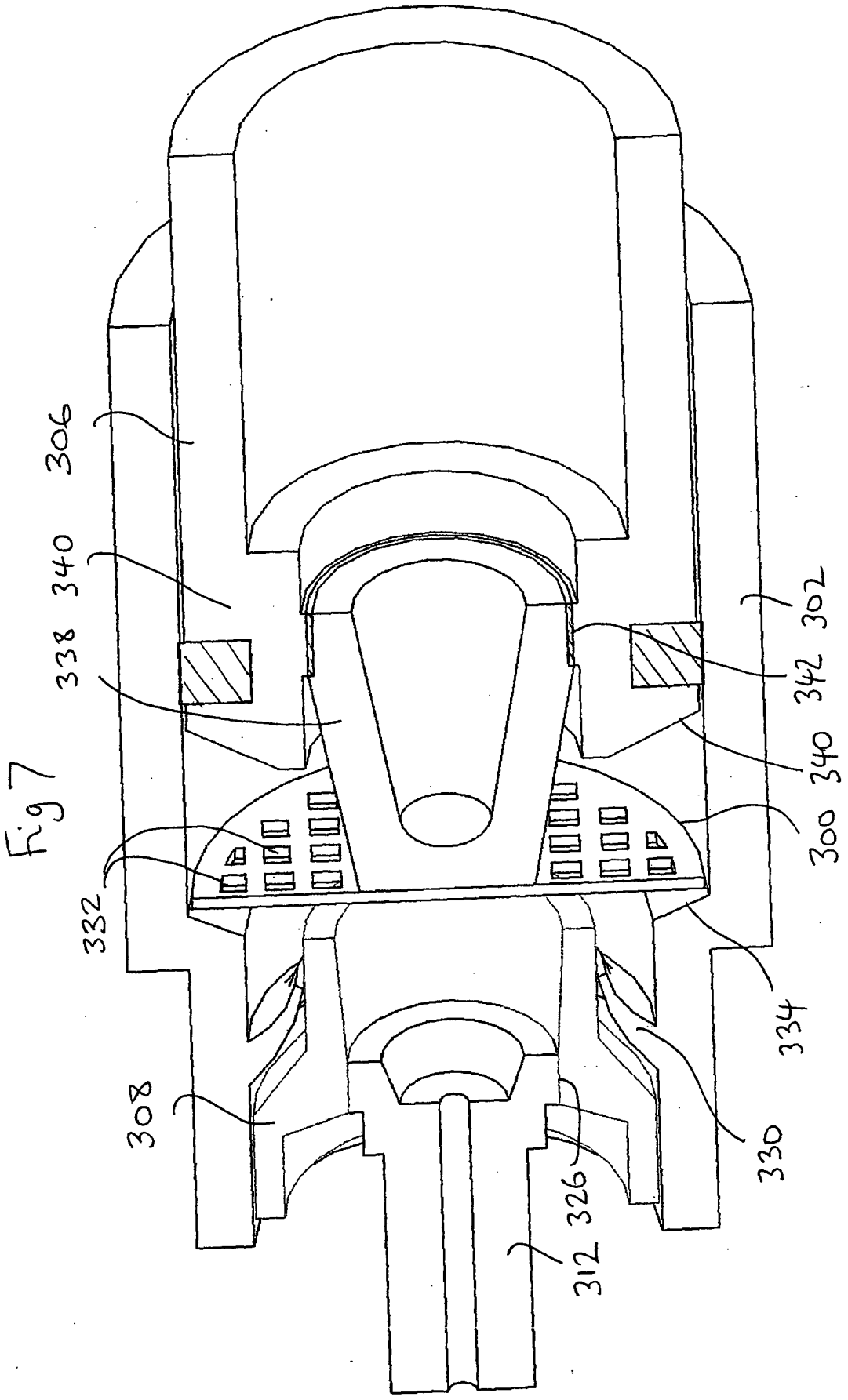
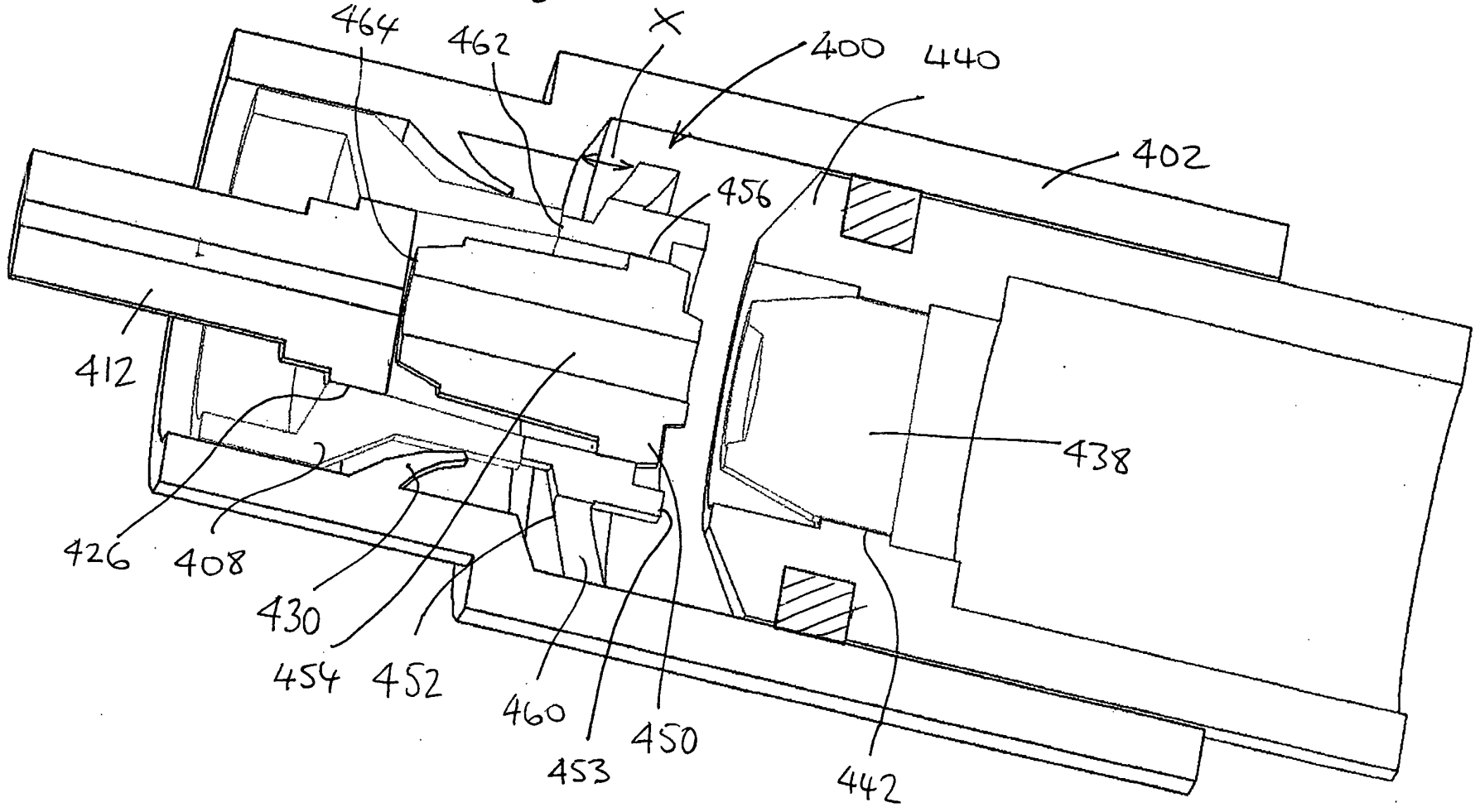


Fig 7

Fig 8


464
462
X
400
440
402
456
412
438
426
408
430
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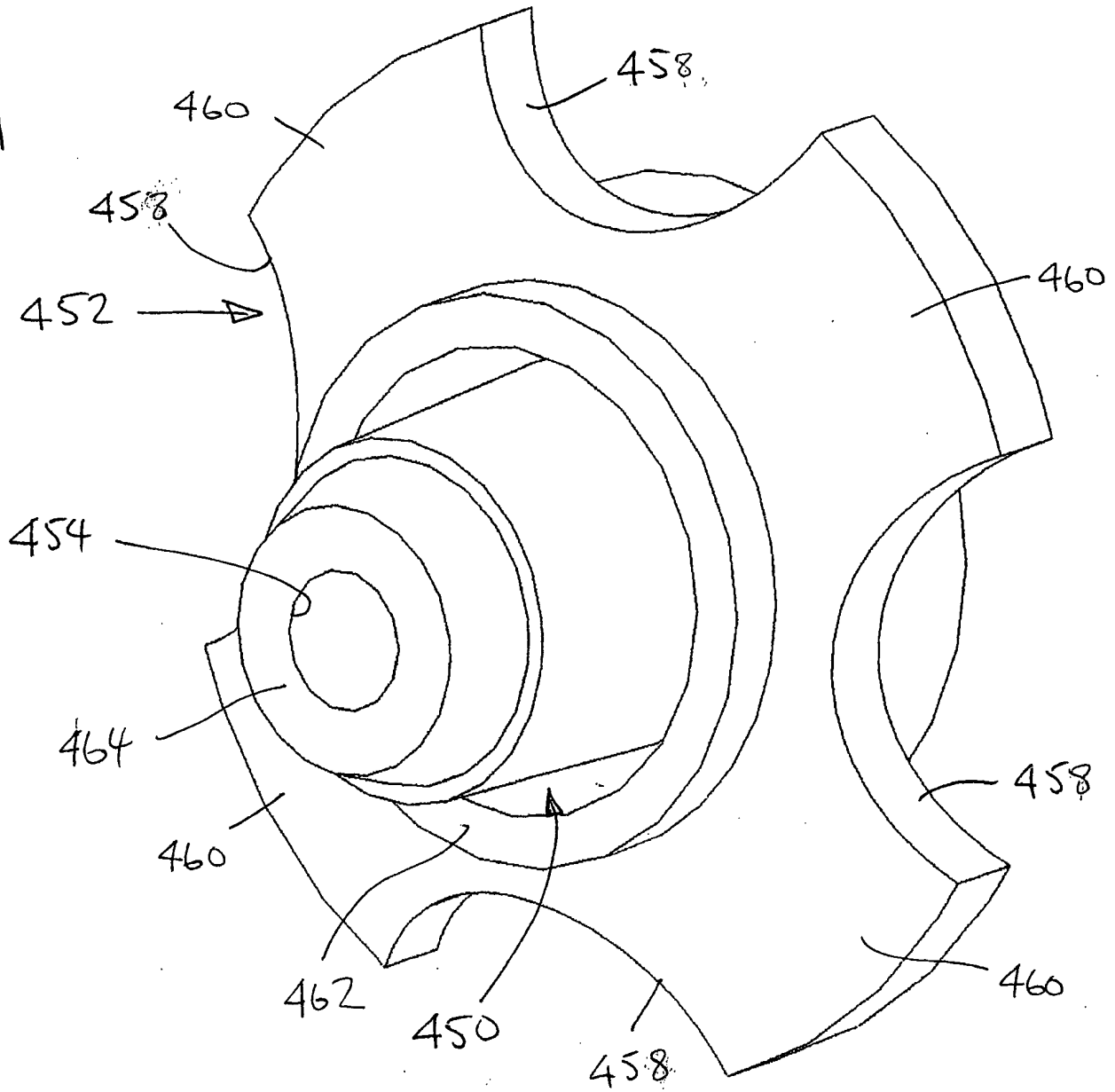
452
460
453
450
442

Fig 9



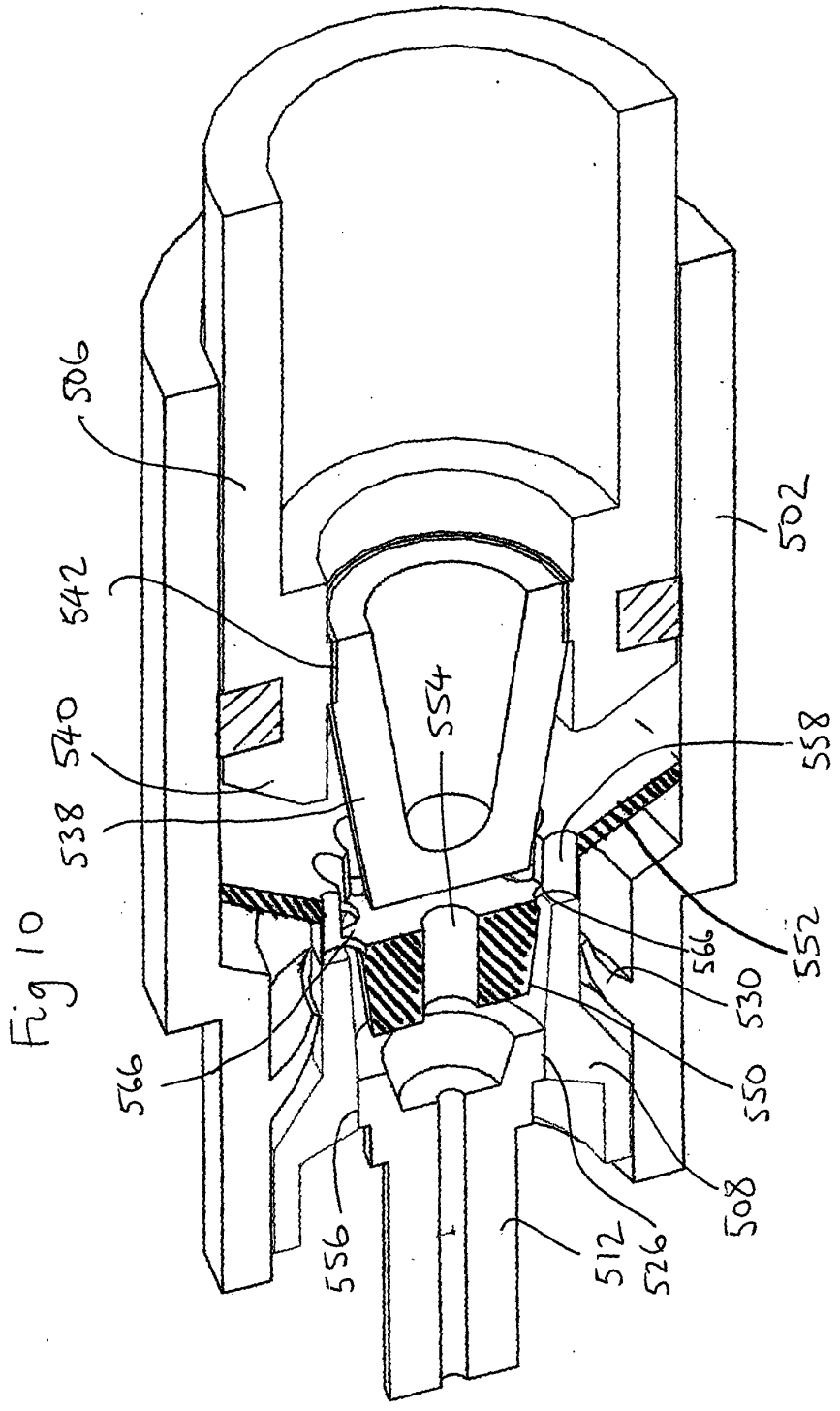


Fig 10

Fig 11